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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,419	11/26/2001	Jim McWhir	096/004	1905

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

10

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/995,419

Applicant(s)
McWhir et al.

Examiner
Joseph Weitach

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 15, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

This application filed November 26, 2001 claims benefit to provisional applications: 60/253,357, filed November 27, 2000; 60/253,443, filed November 27, 2000; and 60/253,395, filed November 27, 2000.

Applicants' amendment filed April 15, 2003, paper number 9, has been received and entered. Claims 2-6 and 9-13 have been amended. Claims 1-22 are pending and currently under examination.

Applicants election with traverse is noted (pages 5-6). In light of the claim amendments a new restriction requirement is set forth below.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-15, drawn to a method of depleting undifferentiated stem cells from a population of cells comprising providing to a population of cells a heterologous polynucleotide comprising a promoter which is expressed in a undifferentiated stem cell operably linked to a sequence which causes expression of a cell surface antigen and depleting undifferentiated cells from the population by separating the cells by binding the cell surface antigen, classified in class 536, subclass 23.1, class 435, subclass 325, class 435, subclass 69.1, class 435, subclass 69.3.

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- II. Claims 1, 2, 4, 9, 11, 13-15, drawn to a method of depleting undifferentiated stem cells from a population of cells comprising providing to a population of cells with an endogenous polynucleotide comprising a promoter which is expressed in a undifferentiated stem cell operably linked to a sequence which causes expression of a cell surface antigen and depleting undifferentiated cells from the population by separating the cells by binding the cell surface antigen, classified in class 536, subclass 23.1, class 435, subclass 325, class 435, subclass 69.1, class 435, subclass 69.3.
- III. Claims 1-3, 5-15, drawn to a method of depleting undifferentiated stem cells from a population of cells comprising providing to a population of cells a heterologous polynucleotide comprising a promoter which is expressed in a undifferentiated stem cell operably linked to a sequence which causes expression of a cell surface antigen and depleting undifferentiated cells from the population by lysing the cells with the addition of complement, classified in 536, subclass 23.1, class 435, subclass 325, class 435, subclass 7.1, class 435, subclass 69.1.
- IV. Claims 1, 2, 5, 9, 11, 13-15, drawn to a method of depleting undifferentiated stem cells from a population of cells comprising providing to a population of cells an endogenous polynucleotide comprising a promoter which is expressed in a undifferentiated stem cell operably linked to to a sequence which causes expression of a cell surface antigen and depleting undifferentiated cells from the

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population by lysing the cells with the addition of complement, classified in 536, subclass 23.1, class 435, subclass 325, class 435, subclass 7.1, class 435, subclass 69.1.

- V. Claims 16-22, drawn to a stem genetically altered stem cell that expresses a carbohydrate antigen not normally expressed by the cells, classified in class 435, subclass 1.1.

Claims 1, 2, 9, 11, 13-15 are generic to groups I-IV and will be examined to the extent that they encompass the elected invention. Claim 4 is generic to both groups I and II and will be examined to the extent that they encompass the elected invention. Claim 5 is generic to both groups III and IV and will be examined to the extent that they encompass the elected invention. Claim 6 is generic to both groups I and III and will be examined to the extent that they encompass the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which use different starting cells containing endogenous or heterologous polynucleotide and to different methods comprising unique steps and materials for depleting undifferentiated cells. Each of the inventions requires different materials to practice

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and requires different and distinct method steps to practice. Further, the methods result in material different outcomes, the methods of groups I and II may result in two populations of cells; differentiated and undifferentiated, and the method of groups III and IV may result in only differentiated cells and complement.

Inventions V and I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells can be used to generate chimeric animals.

Inventions V and II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and methods which do not require the product. The methods of groups II and IV are practiced with cells which have not been genetically altered.

In addition, if any one of groups I, II and V is elected a further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: specifically, X, the nucleic acid sequence which causes expression of a cell surface antigen, comprises expression of cell surface a heterologous receptor or altering the glycosylation of an endogenously expressed cell surface receptor. For the election of species

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Applicants must elect (1) the expression of a heterologous cell surface receptor or (2) the expression one specific glycosyl-transferase enzyme. With respect to the election of the glycosyl-transferase, one specific enzyme must be elected. For example, specific transferases recited are $\alpha(1,3)$ galactosyltransferase (claim 7), ABO transferases group A transferase or group B transferase (claim 8 as set forth in the specification page 43).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 7-13 are generic to both groups I and II, and claims 1-3, 9-13 are generic to all species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, because these inventions are distinct for the reasons given above and the search required for each on of Group I-V is not required or coextensive with each other, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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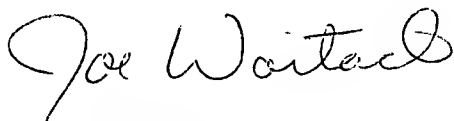
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission.. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

A handwritten signature in cursive script that reads "Joe Woitach".

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